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EXAMINER
MILLER, CHERYL L

ART UNIT	PAPER NUMBER
3738	

Paul J. Maginot
Maginot, Addison & Moore
Bank One Center/Tower
111 Monument Circle, Suite 3000
Indianapolis, IN 46204-5115

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/904,752	MARONEY ET AL.	
	Examiner	Art Unit	
	Cheryl Miller	3738	

-- Th MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-56* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-56* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-56 have been considered but are moot in view of the new ground(s) of rejection. Because prior art used in the previous rejection has been maintained in the current rejection, the examiner will respond to the applicant's arguments.

The applicant has argued that Farey (USPN 6,203,575 B1) does not disclose a scale mechanism having a plurality of distinct values displayed thereon, much less, positioning a trial assembly in the scale mechanism such that a trial offset indicia of a head member of the assembly aligns with one of the values displayed on the scale mechanism. The examiner disagrees. Farey has shown in figure 14 a scale mechanism (1) having a plurality of distinct values displayed thereon. The examiner has interpreted Farey's marking H as being one value and the plurality of openings encircling the perimeter of the scale as additional values, since a value of an opening may be measured or calculated in reference to the marking H as an angular displacement. Also, Farey discloses indicia on a head member (42, 43; fig.6, 11), which aligns with a value on the scale (fig.9). Therefore, the Farey rejection has been maintained.

The applicant has also argued that Farey does not disclose an offset indicia defined in a bearing surface on the trial and final head members, but instead appears to correspond to the direction of displacement defined by a structure located on the underneath side of the prosthesis head. The examiner disagrees. The examiner has interpreted the offset indicia to be holes 42 or 42, which are clearly on the bearing surface of the prosthetic head members (see fig.6, 9, 11). Also, the marking that Farey discloses (col.4, lines 64-67) must inherently be on the bearing

surface, since it is used to align with value H. In order to align, the marking must be seen on the bearing surface, see figure 9, 13. Therefore, the Farey rejection has been maintained.

The applicant has argued that the examiner has not demonstrated that the subject matter on which the Examiner relied on to support the 102 (e) rejection of the claims over Hartdegen et al. (US 2001/0053935 A1) was described in the provisional application 60/201,503 having a filing date of May 3, 2000. The examiner has supplied a copy of provisional application 60/201,503, which contains the subject matter as non-provisional application 09/845,459 relied on for the rejection. Therefore, the priority date of Hartdegen (May 3, 2000) predates the priority date of the current application and the rejection has been maintained

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 45-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Farey (USPN 6,203,575 B1, cited in previous office action). Referring to claims 45-48, 53-54, and 56, Farey discloses a prosthesis implantation method, which includes all limitations recited in the claims. Farey discloses a method (col.1, lines 35-53) comprising providing and positioning a trial assembly (6) in a resected bone (36), the trial assembly (6) including a trial body (7) having a

trial body mating component (9), and a trial head having a trial head member (8) which includes a trial offset indicia (hole, 42, 43, marking, col.4, line 64), and an eccentrically located (col.3, lines 57-60) trial head mating component (11) configured to mate with said body mating component (9, 10), rotating or moving the head (8) relative the body (7) in the resected bone (36) wherein the head (8) covers a resected surface (37) of the resected bone (fig.3, 6, 11; col.3, lines 62-64) and is at a user-selected orientation (col.1, lines 58-63), removing the trial assembly (6), positioning the trial assembly (6) in a scale mechanism (1), (col.1, line 49-50) having a plurality of distinct values displayed thereon (H and divided openings/section each depict a distinct value), or series of gradations (openings) where head offset indicia (43) aligns with one of the plurality of distinct values/gradations (H or divided openings/sections, see figures) on the scale mechanism (1), (col.5, line 41-col.6, line 2), securing or attaching a final head (4) to a final body (3) based on the distinct value/gradation (each opening measuring a position/degree of offset from H, col.5, lines 10-12) and implanting the final prosthesis (2) in the resected bone (36), (col.5, lines 12-17). Farey discloses body and head mating components (11, 9, 10) selected from the group consisting of a bore and a stem (col.3, lines 45-46).

Referring to claims 49-52 and 55, Farey discloses a kit comprising a trial assembly (6) including a trial body (7) having a trial body mating component (9), a trial head (8) having a trial head member which includes a trial offset indicia (43) defined in a first bearing surface (fig.6), and an eccentrically located trial head mating component (11), configured to mate with the trial body mating component (9, 10) or a fastener for securing the trial head to the trial body, and a final prosthesis assembly (2) including a final body (3) having a final body mating component, and a final head (4) having a final head member which includes a final offset indicia (43,

marking, col.5, line 10) on a second bearing surface, and an eccentrically located final head mating component configured to mate with the body mating component (fig.3, 4a). Farey discloses the trial and final body mating components (9, 10, 11) selected from a bore and a stem (col.3, lines 45-46).

Claims 1-2, 4-5, 9-10, 16-17, 19-20, 24, 27-28, 32-33, 35-37, 41-42, and 44-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Hartdegen et al. (Pub. No. US 2001/0053935 A1, cited in previous office action). Hartdegen discloses an implantation method and kit, see underlined portions of the specification, particularly pages 3-5. Referring to claims 1, 17, 45-48, 53-54, and 56, Hartdegen discloses a prosthesis implantation method (0002) comprising providing and positioning a trial assembly in a resected bone, the trial assembly including a trial body (30) having a bore as a body mating component (cavity of stem, 0042), and a trial head (34) having a trial head member, which includes a trial offset indicia (0037), and an eccentrically located trial head stem mating component (projection of head, 0042) configured to mate with the bore on the body, rotating or moving the trial head (34) relative the trial body (30) in the resected bone, wherein the head (34) covers a resected surface of the resected bone and is at a user-selected orientation, removing the trial assembly, positioning the trial assembly in a scale mechanism (70) having a plurality of distinct values displayed thereon (0054, marks, lines, suitable indicia), where the trial offset indicia aligns with one of the values on the scale mechanism (70), securing or attaching a final head (34) to a final body (30) based on the value and implanting the final prosthesis in the resected bone.

Referring to claims 28, 36, 37, 49-52, and 55, Hartdegen discloses a kit comprising a trial assembly including a trial body (30) having a bore (cavity of stem, 0042), a trial head (34)

having an offset indicia on a first bearing surface (fig.2 and 16 show offset indicia, on a surface which bears against the body component 36 or 30, therefore, the surface is a bearing surface) and an eccentrically located stem (projection on head, 0042), the stem configured to be received within the bore and a final prosthesis assembly including a final body (30) having a bore (cavity of stem, 0042), a final head (34) having an offset indicia on a second bearing surface (fig.2 and 16 show offset indicia, on a surface which bears against the body component 36 or 30, therefore, the surface is a bearing surface) and an eccentrically located stem (projection on head, 0042), the stem configured to be received within the bore.

Referring to claim 2, Hartdegen discloses securing the trial head to the trial body when the head is positioned relative to the body at the aligned orientation.

Referring to claims 4, 19, 33, and 42, Hartdegen discloses a trial body (30) portion including a body stem (32), neck, and flat (fig.15), wherein the bore (cavity of stem, 0042) extends through the flat into the neck (fig.15).

Referring to claim 5, Hartdegen discloses a scale mechanism (70) including an indicia surface wherein the plurality of values are displayed on the indicia surface (0054).

Referring to claims 9, 10, 20, 24, 32, and 41, Hartdegen discloses a final head portion including a final head member having an offset indicia and an eccentrically located stem. Hartdegen discloses a final head stem having a male taper, a final body having a bore with a female taper, the stem is advanced into the bore in a friction fit manner (0041, 0042).

Referring to claims 16, 27, 35, 44, Hartdegen discloses implanting the prosthesis into a resected humerus (0056, 0057).

For further clarity, it is noted to the applicant that the "intermediate connecting component" discloses by Hartdegen, may be integral with the head portion, therefore may constitute the eccentric stem of the head (see 0042, wherein an alternative embodiment, a first connector (head stem) is adapted to be at least partially received in a cavity of stem (body portion)-wherein 0043 recites, intermediate connecting component need not be a separate component. In one embodiment, intermediate connecting component is permanently attached to head or stem.)

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-2, 4-17, 19-30, 32-39, and 41-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farey (USPN 6,203,5756 B1, cited in previous office action). Farey discloses a prosthesis implantation method substantially as claimed. Referring to claims 1, 4, 9-10, 17, 19, 24, 32, 37, and 41, Farey discloses a method (col.1, lines 35-53) comprising providing and positioning a trial assembly (6) in a resected bone (36), the trial assembly (6) including a trial body (7) having a body mating component (9), and a trial head having a trial head member (8), and an eccentrically located (col.3, lines 57-60) trial head mating component (11) configured to mate with said body mating component (9, 10), a final head portion (4), and an eccentrically located final head mating component (11), rotating or moving the trial head (8) relative the trial

body (7) in the resected bone (36) wherein the head (8) covers a resected surface (37) of the resected bone (fig.3, 6, 11; col.3, lines 62-64) and is at a user-selected orientation (col.1, lines 58-63). Farey discloses offset indicia on a bearing surface of a trial and final head portion (43, marking, col.4, line 64, col.5, line 10). Farey discloses removing the trial assembly (6), positioning the trial assembly (6) in a scale mechanism (1), (col.1, line 49-50), having a plurality of distinct values displayed thereon (H and divided openings/section each depict a distinct value), where head surface indicia (43, marking) aligns with a value (H or opening) on the scale mechanism (1), (col.4, lines 63-66; col.5, line 41-col.6, line 2), securing or attaching a final head (4) to a final body (3) based on one of the values (col.5, lines 10-12) and implanting the final prosthesis (2) in the resected bone (36), (col.5, lines 12-17). Farey discloses body (9, 10) and head mating components (11) selected from the group consisting of a bore and a stem (col.3, lines 45-46). Farey discloses the claimed invention except for discloses a bore (11) in the head (4, 8) instead of the body (3, 6) and a stem (9, 10) in the body (3, 6) instead of the head (4, 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a bore in the body and stem in the head since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Referring to claims 28, 33, 36, 37, and 42, Farey discloses a kit comprising a trial assembly (6) including a trial body (7) having a trial body mating component (9), a trial head (8) having a trial head member which includes a trial offset indicia (43, marking, col.4, line 64) defined in a first bearing surface (fig.6) and an eccentrically located trial head mating component (11), configured to mate with the trial body mating component (9, 10) or a fastener for securing

the trial head to the trial body, and a final prosthesis assembly (2) including a final body (3) having a final body mating component, and a final head (4) having a final head member which includes a final offset indicia (43, marking, col.5, line 10) defined on a second bearing surface and an eccentrically located final head mating component configured to mate with the body mating component (fig.3, 4a). Farey discloses the trial and final body mating components (9, 10, 11) selected from a bore and a stem (col.3, lines 45-46). Farey discloses the claimed invention except for discloses a bore (11) in the head (4, 8) instead of the body (3, 6) and a stem (9, 10) in the body (3, 6) instead of the head (4, 8). It would have been obvious to one having ordinary skill in the art at the time the invention was made to have a bore in the body and stem in the head since it has been held that a mere reversal of the essential working parts of a device involves only routine skill in the art. *In re Einstein*, 8 USPQ 167.

Referring to claims 2 and 13, Farey discloses securing the trial and final head to the trial and final body respectively when head and body portions are aligned (fig. 3, 6, 11, 9, 10, 13).

Referring to claims 5, 7-8, 11-12, 14, 20, 22-23, 25, 29, and 38, Farey discloses a scale mechanism (1) including an indicia surface (20) and the plurality of distinct values (H and openings) on the indicia surface. Farey discloses a scale mechanism (1) including a channel (21, 17) and locating a trial and final body portion within the channel and locating a trial and final head portion adjacent to the indicia surface (fig.12, 14; col.4, lines 58-61) and aligning the final offset indicia with a value on the indicia surface (col.5, lines 10-12).

Referring to claims 6, 21, 30, and 39, Farey discloses a scale mechanism having an indicia surface possessing markings (marking being an aperture or divider located between each aperture) which depict a clock (fig.9) which is divided into a plurality of sections (each section

being one of the apertures around the perimeter of the disc) and one of the plurality of values (H, K, openings) is identified on one of the sections.

Referring to claims 16, 27, 35, and 44, Farey discloses a resected humerus bone (36) wherein a trial body and final body are configured to be advanced into the humerus (fig.3).

Referring to claims 15, 26, 34, and 43, Farey discloses surface indicia on a head portion of a prosthesis (43, marking, col.4, line 64) in the form of a marking. At the time the invention was made, it would have been an obvious matter of design choice to a person of ordinary skill in the art to use a removable sticker or notch in place of a marking because applicant has not disclosed that a removable sticker or notch provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected applicant's invention to perform equally well with a marking because all perform to visually indicate a position. Therefore, it would have been an obvious matter of design choice to modify Farey to obtain the invention as specified in claims 15 and 26.

Claims 3-4, 18-19, 31, 33, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Farey (USPN 6,203,575 B1, cited in previous office action) in view of Leonard et al. (USPN 6,228,120 B1, cited in previous office action). Farey discloses a trial assembly having a trial body bore portion and trial stem head portion (see above), however does not disclose the bore and stem having threads. Leonard teaches in the same field of trial prostheses, body portions (1) having threaded bores (8) and head portions (20) having threaded stems (17a) in order to provide a fastening means to fix the head portion to the body portion (col.3, lines 63-65; col.6, lines 54-59; col.9, lines 24-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Leonard's teaching

of threaded engagement between head and body components, with the head and body component assembly of Farey, in order to provide a fastening means to fix the trial head portion to the trial body portion.

In an alternative to the above rejection, claims 3-4, 18-19, 31, 33, 40, and 42 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hartdegen et al. (Pub. No. US 2001/0053935 A1, cited in previous office action) in view of Leonard et al. (USPN 6,228,120 B1, cited in previous office action). Hartdegen discloses a trial assembly having a trial body bore portion and trial stem head portion (see above), however does not disclose the bore and stem having threads. Leonard teaches in the same field of trial prostheses, body portions (1) having threaded bores (8) and head portions (20) having threaded stems (17a) in order to provide a fastening means to fix the head portion to the body portion (col.3, lines 63-65; col.6, lines 54-59; col.9, lines 24-37). It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Leonard's teaching of threaded engagement between head and body components, with the head and body component assembly of Hartdegen, in order to provide a fastening means to fix the trial head portion to the trial body portion.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (703) 305-2812. The examiner can normally be reached on Monday through Friday from 7:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on 308-2111. The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3590.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER